APPENDIX B

Financial and Staffing Contributions of the Parties

For NIH:

The NCI will conduct clinical research of Agent under its intramural and extramural research program. The NCI estimates that one to three person-years per years of effort will be dedicated to its participation in the clinical studies, Steering Committee meetings, updates to its IND, compiling data, drug management and monitoring in support of the clinical trials. PHS shall, in addition to its Principal Investigators provide sufficient staffing to execute and fulfill the obligations of the CRADA.

NCI will provide no funding to Company for collaborative research and development pursuant to this CRADA, inasmuch as financial contributions by the U.S. government to non-Federal parties under a CRADA is prohibited under the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710a(b)(1)).

For Collaborator:

Personnel:

Collaborator intends to commit one to three person-years per years of effort to permit the timely execution of the studies implemented under this CRADA. More specifically, this staffing shall include Collaborator full-time employees, consultants to the company, external contract agencies and contract research organizations.

Clinical Data Collection Support:

Clinical Trial Monitoring Services (CTMS) will be reimbursed by Collaborator for the cost of reformatting and reproducing the Raw Data if Collaborator requests copies of Raw Data from CTMS in a format which is different from the format as set forth in CTMS' contract with Cancer Therapy Evaluation Program (CTEP), DCTD, NCI.

Any arrangement which involves the collection of more than the summarized data (Summary Data) provided annually to the DCTD will be at the expense of the Collaborator. Should Collaborator choose to review copies of Patient Research Records, such a review will be at Collaborator expense and occur after agreement and notification of the investigators by NCI and only after all patient identifiers have been removed.

Collaborator may make only reasonable requests for access to investigator data. The information will be provided according to a mutually agreed upon plan between the NCI, the Collaborator, and the investigator(s), and only in accordance with the guidelines and policies of the responsible Data Monitoring Committee, if there is one. Collaborator will be responsible for the costs associated with any unusually burdensome requests, such as a request that the data be provided in a format which is different than that normally collected.

Agent:

Collaborator will provide to NCI, free of charge, *[(bulk) or (formulated)] Agent* in sufficient quantities to complete the studies, both pre-clinical and clinical, planned pursuant to this CRADA. Additionally, Collaborator will provide *[bulk) or (formulated)] Agent* in sufficient quantities to complete any other studies sponsored by the NCI under this CRADA that are mutually agreeable to NCI and Collaborator. Furthermore, Collaborator will provide Certificates of Analysis to NCI for each lot of finished product provided which verify the suitability of Agent for use in the scheduled preclinical studies or clinical trial protocols.

Funding:

Collaborator agrees to provide up to $_____ per year for transportation and lodging costs to support the participation of DCTDC staff at selected scientific or development meetings, where such participation will substantially foster development of Agent. Collaborator and DCTD must mutually agree to the activities that are appropriate under this Agreement. Travel costs are limited by the Federal Travel Rules and Regulations for all government staff whether paid for by government funds or private Collaborators.

Any additional funding will not be added to this CRADA without an appropriate written executed amendment pursuant to Article 13.6.

No funds provided under this CRADA by Collaborator will be used by NCI to pay the salary of full-time tenured federal employees.

Payment Schedule:

The CRADA Central Accounting Number (CAN) will be supplied to Collaborator shortly after execution of this CRADA. Prior to notification of an executed CRADA, payments should be made by check payable to the National Cancer Institute and sent to the Office of Technology Development, NCI, to the attention of the "CRADA Funds Coordinator." Payments should clearly reference the NCI CRADA Number and Title: CACR-___, "Clinical Development of _____."

Payments will be made annually, the first payment due within 30 days of the execution of this CRADA. Checks should be made payable to the National Cancer Institute and addressed to CRADA Funds Coordinator; Office to Technology Development, NCI; 6120 Executive Blvd., Executive Plaza South, Ste. 450; Bethesda MD 20892-7182 with a clear reference to the NCI CRADA Number and Title: CACR-____, "Clinical Development of _____."